

## **Stem Cell Board Sends "Strong, Unambiguous Message"; Approves Bold New Vision for the Future**

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**Los Angeles, CA** – It is a roadmap unlike any other, laying out a series of bold, innovative ideas and ambitious goals for CIRM, California's stem cell institute, to achieve over the next five years. Today the CIRM Board approved that vision, giving its unanimous "enthusiastic" support to the new Strategic Plan.

The Strategic Plan creates a new approach to funding stem cell research, one where each program links to another, building a seamless system designed to dramatically accelerate the development of stem cell therapies to patients with unmet medical needs.

"Our goal in developing this Strategic Plan was to create a clear vision for the next five years of the Institute," says C. Randal Mills, PhD., CIRM's President and CEO. "We have around \$900 million left to work with and we wanted a plan that used that money to produce the greatest possible impact for our patients. We didn't want something 'good enough', we wanted something 'transformational'. This plan is extremely ambitious, and not without risk, but with focus and determination we will accomplish great things."

The Plan, which was put together after extensive consultations with researchers, companies, patient advocates and other stakeholders, has a number of goals, including:

- 50 additional new clinical trials in 5 years including 10 for rare or orphan disorders and 5 in conditions affecting children
- Enacting a new, more efficient federal regulatory approval process for stem cell treatments
- Introducing 50 new therapeutic candidates or devices into the development pipeline
- Reducing the time it takes to move a stem cell treatment from the earliest Discovery stage into a clinical trial by 50%
- Increasing the number of projects moving to the next stage of development by 50%
- Pairing at least 50% of our unpartnered clinical stage projects with commercial partners

New innovations include a Translating Center to help researchers with the work needed to move their programs through the regulatory approval process, and an Accelerating Center to provide the expertise needed to develop and carry out successful clinical trials. The Plan attempts to stimulate greater industry involvement by creating public-private partnerships to advance CIRM-funded research and technologies, taking them out of the lab and into the market place.

It also includes financial incentives to encourage researchers at the Discovery level to move promising research to the next level.

One of the key elements in making all this work is changing the regulatory process that governs stem cell research. The current system was developed to regulate drugs and more conventional therapies and is not appropriate for stem cell treatments. The Strategic Plan calls for CIRM to work with the FDA, patient advocates, researchers and other stakeholders to develop a new, faster and more efficient way of regulating stem cell therapies, one that helps rather than hinders their progress to the clinic.

The Plan lays out clear performance metrics to enable the CIRM Team to continually evaluate progress and make any necessary corrections or improvements.

"With this plan CIRM is aligned," says David Higgins, PhD, the Patient Advocate for Parkinson's on the CIRM Board. "One of the most important things any organization needs to succeed is clarity of purpose. This plan provides that clarity for us, identifying where we want to go and how we are going to get there, and the Board wanted to send a strong, unambiguous message by unanimously supporting it. The beauty of the plan lies in the fact that each part of the machine integrates with the next, creating a whole that really is more than the sum of its parts and that dramatically drives the field forward."

The Strategic Plan focuses on the next five years because CIRM has enough money left to continue funding for that period, however, that does not mean the Institute is not also looking at developing other sources of revenue to enable it to continue its work.

Jonathan Thomas, Chair of the CIRM Board, has been working to ensure there are enough administrative funds (which are separate from

the research funding) to continue the oversight of research should the agency not be refunded. To date Thomas has secured \$7 million of the estimated \$30 million the Institute will need for the responsible oversight of its award portfolio. These gifts come from the William K Bowes, Jr. Foundation (\$5m) and from Franklin P. Johnson (\$2m).

"The last thing we want is for this work to come to a grinding halt," says Thomas. "We want to do everything we can to ensure that not only can we continue to fund this essential research, but that we are also here to be able to help guide that work and ensure it is on target. When we invest in a project we become partners with the company or researchers and do everything we can to help them succeed. The money we are raising to support the administrative side of CIRM means we can continue to offer that vital support for many years to come."

**About CIRM**

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$3 billion in funding and approximately 300 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information go to [www.cirm.ca.gov](http://www.cirm.ca.gov)

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